Office's attention is respectfully directed to M.P.E.P. § 821.04, which provides for rejoinder of process Claims in such a case.

Note particularly that rejoinder under M.P.E.P. § 821.04 does not depend upon whether the original election was made with or without traverse.

4-5. The August 22, 2001 Information Disclosure Statement

The Office stated that while patent application 09/830,194 had been considered, its citation had been crossed out because an application is not a proper reference to print on the face of a patent. Although the Office cited no authority in support of this position, the Office's statement shows that the prosecution history will reflect that Applicant has fulfilled any duty of candor that may exist respecting the '194 application, and that the Office has considered that application in connection with the examination of the present application.

7. The Claim Objections

The Office objected to Claims 64, 66, 69, 70, 77, 79, and 81 on the ground that the phrase "A rice plant" should instead read --The rice plant-- to denote that the dependent claims further limited the plant recited in the parent claim. Although no authority was cited in support of this position, in the interest of expediting prosecution the suggested Claim amendments have been made.

These amendments are purely formal in nature, and are not intended to alter the scope of any of the Claims in any manner.

It is noted that the Office included "Claim 69" in this objection. In context, it appears that this reference resulted from a typographical or clerical error, and that --Claim 68-- was intended instead.

Applicant has made analogous amendments to process Claims 72 and 73, which remain in the application.

8-9. The § 112, Second Paragraph Rejections

Claims 62, 64, 66, 69, 70, and 81 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite on various grounds. Specific grounds of rejection were given only for Claims 62 and 81. It is assumed that the remaining Claims were rejected due to their dependence from independent Claim 62.

It is noted that the Office included "Claim 69" in this ground of rejection. In context, it appears that this reference resulted from a typographical or clerical error, and that --Claim 68-- was intended instead.

The conjunction "and"

Claim 62 was said to be "indefinite because after both subsections (a) and (b), the conjunction 'and' is used making the claim unclear if one is to select (a) and (b); or (a) and (c); or (a) and (b) and (c)."

With all respect, this ground of rejection is not understood. The limitations "(a) and (b) and (c)" mean exactly that -- all three limitations must be satisfied. It is not seen where any ambiguity exists.

By contrast, in the absence of clarification a hypothetical limitation such as "(a) and (b) or (c)" might be ambiguous: such an expression might be interpreted as "[(a) and (b)] or [(c)] "; alternatively, it might be interpreted as "[(a)] and [(b) or (c)] ." But an ambiguous limitation such as this hypothetical one does not appear in Claim 62.

It is not understood how, as used in Claim 62, the word "and" could be construed instead to mean "or."

It is respectfully submitted that the conjunction "and" is used in Claim 62 in an unambiguous manner, and that this ground of rejection should be withdrawn.

Derivatives

Claims 62 and 81 were said to be indefinite in their use of phrases such as "is a derivative of a rice plant" because there are many ways to derive a rice plant.

It is certainly true that there are many ways to derive a rice plant. But that observation does not mean that the Claim is indefinite.

It should be kept in mind that a claim is definite if its scope is clear. If the metes and bounds of a claim are clearly ascertainable, then the claim, no matter how broad, may not properly be rejected under § 112, second paragraph. As stated by the Court of Customs and Patent Appeals, one of the two predecessor courts to the Court of Appeals for the Federal Circuit, if each of the limitations of a claim is definite, then the claim is definite and may not be rejected under section 112, second paragraph. *In re Goffe*, 526 F.2d 1393, 1397-98; 188 USPQ 131, 135 (CCPA 1975).

It is axiomatic that a patent applicant is entitled to be his own lexicographer. The present specification defines what is meant by a "derivative" of a herbicide-resistant plant, and confirms that the expression is intended to have a broad, but definite, interpretation. See page 30, lines 18-26:

> Unless otherwise clearly indicated by context, the "progeny" of a plant includes a plant of any subsequent generation whose ancestry can be traced to that plant.
>
> Unless otherwise clearly indicated by context, a "derivative" of a herbicide-resistant plant includes both the progeny of that herbicide-resistant plant, as the term "progeny" is defined above; and also any mutant, recombinant, or genetically-engineered derivative of that plant, whether of the same species or of a different species; where, in either case, the herbicide-resistance characteristics of the original herbicide-resistant plant have been transferred to the derivative plant. Thus a "derivative" of a rice plant with a resistant AHAS enzyme would include, by way of example and not limitation, any of the following plants that express the same resistant AHAS enzyme: F_1 progeny rice plants, F_2 progeny rice plants, and F_{30} progeny rice plants.

A Claim is definite if its scope is clear, regardless of how broad the Claim might be. The meaning of "derivative" as used in these Claims is clear. It is respectfully submitted that this ground of rejection should be withdrawn.

"the herbicide resistance characteristics of the plant"

In Claim 81, the phrase "the herbicide resistance characteristics of the plant" was said to be indefinite because it was said to be unclear whether the limitation required that the herbicide resistance characteristics come from the deposited line ATCC 75295, or might come from another plant having the same characteristics.

It is respectfully submitted that the specification's definition of "derivative" quoted above resolves any ambiguity that might otherwise exist on this point. Claim 81 requires not only that the rice plant have "the herbicide resistance characteristics of the plant with ATCC accession number 79295," but also that the plant must be a "derivative of the plant with ATCC accession number 79295." As stated in the definition of "derivative" quoted above, it is required that "the herbicide-resistance characteristics of the original herbicide-resistant plant have been transferred to the derivative plant."

Thus there is no ambiguity concerning the point raised by the Office, and it is respectfully submitted that this ground of rejection should be withdrawn.

§ 112, Second Paragraph Summary

It is respectfully submitted that all § 112, second paragraph rejections should be withdrawn.

10. The § 112, First Paragraph Rejections

The February 11, 2003 Office Action entered three grounds of rejection under 35 U.S.C. § 112, first paragraph: a "written description" rejection, a rejection pertaining to the various deposits of seeds under the Budapest Treaty, and an "enablement" rejection. Each of the three grounds of rejection is discussed below.

11. The Written Description Rejection

Claims 62, 64, 66, 68, 70, 75, 77, 79, and 81 were rejected as containing subject matter that lacked an adequate written description in the specification.

Although the February 11, 2003 Office Action cited M.P.E.P. § 2163 in support of this ground of rejection, the Office Action apparently overlooked the "strong presumption" recognized by M.P.E.P. § 2163, subpart (I)(A), first paragraph: "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." (citation omitted)

The preliminary amendment that was filed on August 22, 2001 in no way alters this "strong presumption," because nothing in the Office's written description rejection dealt with any limitation that was altered by the Preliminary Amendment. Furthermore, as was discussed in greater detail in the Preliminary Amendment, those amendments primarily concerned either clarifications that were not intended to change the scope of the claims; or concerned incorporating the substance of Claim 74 as originally filed into independent Claim 71. There was, however, one part of the amendment to Claim 71 that did change its scope. Likewise, the amendments in the present paper concern formal matters only, and are not intended to change the scope of the Claims in any manner.

Thus, with the arguable exception of the one part of the Preliminary Amendment that altered the scope of Claim 71, all Claims continue to be entitled to the "strong presumption" of M.P.E.P. § 2163 that an adequate written description is present. With all respect, the February 11, 2003 Office Action did not rebut this strong presumption.

The Office Action at page 5 cited another portion of M.P.E.P. § 2163, subpart (I)(A) for the proposition that a "claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function."

But the quoted section from the M.P.E.P. does not purport to present an absolute rule. Rather, it is intended to alert one to a possibility, a possibility that may or may not exist, depending on the facts of a particular case: "The claimed invention as a whole ***may*** not be adequately described . . . ." (emphasis added)

The specification in fact describes a correlation between the structure and the function of the whole organism: a rice plant that expresses a herbicide resistant AHAS enzyme

(structure) is thereby made resistant to certain herbicides (function). See the present specification, page 7, lines 13-18.

But more importantly, it should be kept in mind that the structure-function question is only subsidiary. As previously discussed, the purpose of this subsidiary question is merely to alert one to a particular possibility, a possibility that should be evaluated in light of the individual circumstances. The principal, underlying question is the following: "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." M.P.E.P. § 2163, subpart (I), second paragraph, citation omitted. The present specification clearly demonstrates that the Applicant had possession of the claimed invention.

As stated in M.P.E.P. § 2163, subpart (II)(A)(3)(a), first paragraph: "Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention." See also M.P.E.P. § 2163, subpart (II)(A)(3)(a)(ii), first paragraph: "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice . . . ."

A sufficient written description for a claimed genus exists where, as is the case here, the specification gives a sufficient description of the reduction to practice of a representative number of species. The present specification describes not just paper examples, not just a single example, not just a couple of examples. Rather, the specification describes, in detail, the actual reduction to practice of twenty-seven species of herbicide resistant rice in accordance with the present invention. See, e.g., page 8, line 1 through page 11, line 31. All but five of these twenty-seven species were deposited with ATCC. See, e.g., page 9, line 25 through page 10, line 10; and page 11, lines 7-21. (Note that the apparent "volunteers," herbicide resistant lines that appeared to be identical to the earlier ATCC 97523 line, possibly from seeds lying dormant in the soil between seasons, were not counted as being among these twenty-seven species. Page 24, lines 1-4.)

The actual reduction to practice of twenty-seven species, with ATCC deposits of twenty-two of those species, is more than ample to support generic claims.

The preceding discussion should alone suffice to demonstrate that the present application satisfies the written description requirement. But for the sake of completeness, and in the event that prosecution of this application might thereby be accelerated, below are brief answers to three questions raised on pages 5 and 6 of the February 11, 2003 Office Action.

(i) The Office Action asserted that the Applicant had not described the specific mutations. The mutations are those that result in: a rice plant **(1)** that "is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant" and **(2)** that expresses "a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant." Thus whether a particular rice plant satisfies these limitations might, for example, be identified by a straightforward, two-part test: **(1)** determine whether the rice plant exhibits resistance to such a herbicide, under conditions that inhibit a control rice plant lacking herbicide resistance; and **(2)** determine whether the rice plant expresses an AHAS enzyme that is resistant at the enzyme level to normally inhibitory levels of herbicide. Examples of both types of tests are given in the specification. For example, the plant-level test is exemplified by the experiments described on pages 12-23; and the enzyme-level test is exemplified by the assays described on page 7, lines 13-30.

(ii) The Office Action asserted that the Applicant had not described how to distinguish the claimed herbicide resistant rice plants from other herbicide resistant rice plants. Paragraph *(i)* above describes one way in which one might readily determine whether a particular rice plant satisfies the functional limitations of the claims. In addition to the functional limitations, certain of the product claims are written in product-by-process format. Whether the process limitations in a product-by-process claim must be satisfied in order for an accused product to infringe is a question on which the jurisprudence has varied over the years. Applicant will not attempt to predict where the caselaw on this question might be at

some point in the future. However, to the extent that the governing law might point to the conclusion that such process limitations must be satisfied, then as a practical matter it would be straightforward to determine whether a particular rice plant is a derivative of a rice plant obtained by the recited process. Before the present invention was reduced to practice, no source of AHAS herbicide resistance in rice was known -- whether naturally occurring or artificially induced -- that satisfied the functional limitations of the claimed inventions (as discussed further below in the response to the "prior art" rejections). Thus a rice plant that satisfies the functional limitations of the claims should be presumed to have been made by the recited process, in the absence of satisfactory evidence to the contrary. If only one process is known for making a particular product, and a person making and selling the product cannot demonstrate that the product was made by a different process, then it is fair to presume that the product was made by the only known process for making such things.

In fact, the patent statute has codified this presumption in the case of process patents. 35 U.S.C. § 295 provides that in an action for infringement of a process patent, if the court finds that a substantial likelihood exists that the product was made by the patented process, and if the plaintiff has made reasonable efforts to determine what process was actually used but was unable to do so, then the product shall be presumed to have been made by the patented process, and the burden of establishing otherwise shall be on the party asserting that it was not so made. Logically, the same principle should apply by analogy to the "process limitations" of a product-by-process claim, to the extent that the process limitations must be satisfied in order for a product to infringe such a claim.

Furthermore, it should be kept in mind that it is a nearly universal practice that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (except for a small number of proprietary hybrids). See, for example, the present specification at page 8, lines 11-16 and page 10, lines 12-15, where the present inventor disclosed the "parentage" of the several embodiments of this invention that had been reduced to practice as of the filing date of this application. While it may not have been strictly necessary to do so for purposes of satisfying the patent statute, this information was nevertheless supplied as second nature by the inventor, as it is customary among rice breeders

to do so. Similarly, as a practical matter one is very likely to know the pedigree of any publicly released rice cultivar.

For either of these reasons one should readily be able to determine the ancestry of a rice variety accused of infringing these claims should it be necessary to do so (which it may not be): (1) a presumption that a rice plant that satisfies the recited herbicide resistance characteristics was produced by the recited method, in the absence of rebuttal evidence showing otherwise; and (2) the nearly universal practice in the art of publicly disclosing the ancestry of new rice cultivars.

(iii) The Office Action noted that Applicant does not know the mechanism of herbicide resistance in the ATCC 75295 line, other than that it does not involve a resistant AHAS enzyme. A limitation concerning ATCC 75295 appears only in dependent Claim 81, where an "ATCC 75295 derivative" limitation is added to the limitations of independent Claim 75. The patent law imposes no requirement that an inventor must understand why an invention works. It suffices that the invention does in fact work. To the present day, the mechanism of herbicide resistance in ATCC 75295 is not understood. However, as the Office has previously recognized -- for example, in issuing patent 5,545,822, which contains claims directed to rice line ATCC 75295 and its derivatives and progeny -- an inventor need not be able to explain why an invention works in order for the invention to be patentable. Note further that, unlike some of the broader limitations appearing in other Claims, the "ATCC 75295" limitation of Claim 81 is not directed to a generic description of a category of herbicide resistance; rather, that limitation requires specifically that "said plant is a derivative of the plant with ATCC accession number 75295, and said plant additionally has the herbicide resistance characteristics of the plant with ATCC accession number 75295." Thus this limitation does not go beyond the written description.

Written description summary

It is respectfully submitted that the written description rejection should be withdrawn.

12. The Budapest Treaty Seed Deposits

Claims 62, 64, 66, 68, 70, 75, 77, 79, and 81 were rejected based on objections to the various deposits of seeds with the American Type Culture Collection.

Without conceding the validity of the Office's objections, the undersigned confirms, over his signature and registration number appearing below, that each of the seed deposits with the American Type Culture Collection that is described in the present specification on pages 9-11 was made under the Budapest Treaty, and that all restrictions on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on the present application.

It is respectfully submitted that this ground of rejection has been overcome or is otherwise now moot.

13. The Enablement Rejection

Claims 62, 64, 66, 68, 70, 75, 77, 79, and 81 were rejected as containing subject matter that was not enabled by the specification. The Office presented arguments concerning two principal points, the first of which (herbicide-resistant phenotype) apparently applied to all Claims examined, and the second of which (derivatives of ATCC 75295) apparently applied to dependent Claim 81 only. These two points are discussed separately below.

Herbicide-Resistant Phenotype

On pages 8 and 9, the Office Action asserted: **(a)** that the specification did not teach what mutations had occurred in the exemplified plants, but instead only demonstrated that herbicide-resistant phenotypes had been generated; and **(b)** that the specification did not teach how to distinguish the claimed plants from other herbicide-resistant rice plants.

Point **(b)** was discussed above in the remarks concerning the written description rejection. For the same reasons given there -- reasons that will not be repeated in the interest of brevity -- it is respectfully submitted that the specification teaches one of ordinary skill in the art how to distinguish the claimed plants from other herbicide-resistant rice plants, without undue experimentation.

Point **(a)** did not have a counterpart in the written description discussion. The Office Action asserted that the specification did not teach what mutations had occurred in the exemplified plants, but instead had demonstrated only that herbicide-resistant phenotypes had been generated. In support of this ground of rejection, the Office Action cited a chapter by Barrett to the effect that P450 enzymes and glutathione transferase enzymes might sometimes play a role in resistance to herbicides such as imazethapyr.

Applicant notes initially that Barrett is not prior art. As discussed in greater detail below under heading No. 17, the present application is entitled to the benefit of a 1998 provisional filing date. Barrett was published in 2000, and is therefore not prior art.

Applicant acknowledges, however, that merely removing Barrett as a citable reference would not necessarily invalidate the Office's basic point. Whether or not Barrett is available as a reference, it would still be the case that the mere observation of a herbicide-resistant phenotype would not necessarily demonstrate the presence of a resistant AHAS enzyme. Herbicide resistance might instead be due to another mechanism. As discussed in greater detail below under heading No. 18, Applicant's own work pertaining to the ATCC 75295 line demonstrates that it is possible for rice to express an AHAS-resistant phenotype without necessarily possessing a herbicide-resistant AHAS enzyme.

Nevertheless, Applicant has now demonstrated that, in fact, several of the exemplified rice lines do have resistant AHAS enzymes. Furthermore, none of the lines that have been tested has been found to lack a resistant enzyme.

As of the filing date of the "parent" application, the Applicant had not yet conducted enzyme-level assays of the exemplified rice lines. The present application states at page 7, lines 13-18:

> Although the resistance mechanisms of the new rice lines have not yet been fully characterized, it is believed that the herbicide resistance of the novel rice lines is most likely attributable to different mutations of the AHAS enzyme, mutations resulting in enzymes expressing direct resistance to levels of herbicide that normally inhibit the wild-type AHAS enzyme. That the resistance is due to mutant AHAS enzymes (rather than another route such as gene copy number, enhanced promoter activity, metabolic degradation, etc.) will be confirmed using *in vitro* assays.

Then followed, on page 7, lines 18-30, a description of assays that could be used to test enzyme activity both in the presence and in the absence of herbicide.

These enzyme-level assays have subsequently been conducted on several of the exemplified rice lines, and the inventor's expectations have been confirmed. Each of the exemplified, herbicide-resistant rice lines that has been tested to date has been found to express resistance to AHAS-acting herbicides at the enzyme level. See the inventor's subsequently-published international patent application WO 01/85970, pages 37-39. (Because the cited international application is rather lengthy, only the publication cover sheet and cited pages 37-39 are being supplied with the enclosed IDC. At the Office's request, Applicant would be happy to supply a copy of the full published international application.)

These data confirm that the Applicant has in fact discovered a reproducible method for generating multiple mutant rice lines that are resistant to AHAS-acting herbicides at the enzyme level. The specification enables a worker of ordinary skill in the art to practice the claimed inventions without undue experimentation.

Derivatives of ATCC 75295

One enablement ground of rejection applied only to Claim 81, which is the only pending Claim containing a limitation that refers to ATCC 75295. It appears that this rejection was based on an erroneous interpretation of the Claim language. The Office Action asserted at page 10 that the herbicide resistance characteristics of the plant with ATCC accession number 75295 "can be introduced from another rice plant." Because the herbicide resistance mechanism of ATCC 75295 is currently unknown, the Office Action asserted that undue experimentation would be required to do so.

But Claim 81 specifically requires that the plant in question must be "a derivative of the plant with ATCC accession number 75295." As discussed above in connection with the § 112, second paragraph rejections, the specification provides a detailed definition of what it means for one plant to be a "derivative" of another. That discussion will not be repeated here in the interest of brevity, but it is respectfully submitted that the response to the § 112, second

paragraph rejection pertaining to "derivatives" also answers the enablement rejection of Claim 81. In brief, Claim 81 requires that the rice plant must, among other things, have herbicide resistance characteristics that may be traced back to the deposited line ATCC 75295.

Enablement Summary

It is respectfully submitted that all grounds of rejection pertaining to enablement should be withdrawn.

14-15. The § 102(b) Rejection

Claims 62, 64, 66, 68, and 70 were rejected under 35 U.S.C. § 102(b) as being anticipated by Terakawa.

Terakawa does not disclose, as required by independent Claim 62, a "herbicide-resistant rice plant, wherein: **(a)** the growth of said herbicide-resistant plant is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant . . . ."

Instead, Terakawa discloses a rice mutant that was said to be resistant to the herbicide bensulfuron methyl. No resistance to other herbicides is disclosed.

However, bensulfuron methyl does not "normally inhibit the growth of a rice plant." Terakawa acknowledges as much in the first paragraph on page 268: "However, BSM [bensulfuron methyl] inhibits the root elongation of rice seedling in paddy field occasionally. Although BSM toxicity to rice is not severe, it affects to the initial growth of the rice plants." In short, Terakawa mentions one side effect of bensulfuron methyl on rice that is seen only "occasionally," and unequivocally states that "toxicity to rice is not severe."

It is probably the case that almost any commercially-sold herbicide could be applied to a crop for which the herbicide is labeled in a concentration, or at a time, or in a manner, that would cause the herbicide to have an adverse effect on the crop that it normally protects from weeds. However, the possibility of such misuse or of side effects does not make the

herbicide one "that would normally inhibit the growth of a rice plant," as required by independent Claim 62.

What might not be apparent from reading the Terakawa paper in isolation is that bensulfuron methyl is a herbicide that is regularly applied to ordinary rice fields, i.e., rice that is not considered "herbicide resistant." Enclosed with the new Information Disclosure Citation is "DuPont™ Londax® Herbicide," Section 3 Specimen Label No. H-64161, available on March 4, 2003 from http://www.dupont.com/ag/labelmsds_search.html (2001). Londax® is DuPont's trademark for the herbicide bensulfuron methyl, the same herbicide discussed in Terakawa. This "label" makes it clear that Londax® is intended for use on rice. To take just one example, see the first sentence under the heading "General Information" on page 2: "LONDAX® herbicide is a dry flowable formulation that is used for selective preemergent and postemergent weed control in rice."

See also the Croughan *Louisiana Agriculture* 1994 paper, which the February 11, 2003 Office Action cited at page 13 (albeit for a different point). The second full paragraph in the first column of page 26 states: "One of these herbicides is already used in rice production. The herbicide bensulfuron (Londax), applied at 1 ounce per acre, effectively controls several broadleaf weeds in rice fields. Rice is inherently resistant to Londax and therefore not injured by its application."

In the DuPont label, note also the seventh "bullet point" near the top of the second column of page 3: "Most crops other than rice are highly sensitive to LONDAX® .. Avoid all direct or indirect (such as spray drift) contact with nontarget crops (or land scheduled to be planted with crops), as injury may result."

The label also mentions that the potential for side effects exists in rice, which is hardly an unusual situation for a herbicide. On page 2, in the third paragraph under "Environmental Conditions and Biological Activity," appears this statement: "Occasionally, treated rice may suffer temporary chlorosis and/or growth retardation after treatment with LONDAX®. These symptoms, which intensify in cold water and at high ambient temperatures, are normally temporary and disappear within two to three weeks after application." Thus it appears that Terakawa may have found a way to lessen some of these

"occasional" side effects in rice; but Terakawa did not discover resistance to a herbicide that "would normally inhibit the growth of a rice plant."

Terakawa does not anticipate the claimed inventions. It is respectfully submitted that the § 102(b) rejection should be withdrawn.

17. The § 102(e) / § 103(a) Rejection over the Croughan '704 Patent

All Claims that have been examined to date were rejected under 35 U.S.C. § 102(e), or in the alternative under 35 U.S.C. § 103(a), over Croughan, U.S. Patent 5,773,704.

The '704 patent is not prior art to the present application. Rejections under §§ 102 and 103 may not be based on the '704 patent.

The '704 patent is not prior art under § 102(e). Subsection 102(e) refers in pertinent part to "a patent granted on an application for patent by another . . . ." The '704 patent is not a patent by "another." To the contrary, the sole inventor in both the '704 patent and the present application is Dr. Timothy P. Croughan.

Although the Office did not cite § 102(b), in the interest of accelerating prosecution it is respectfully noted that the '704 patent would not be citable under § 102(b) either. Subsection 102(b) refers in pertinent part to an invention that "was patented or described in a printed publication . . . more than one year prior to the date of the application for patent in the United States . . . ." The '704 patent issued on June 30, 1998. Under §§ 120 and 119(e), the present application is entitled to the priority of application 60/107,255, filed on November 5, 1998. See the August 22, 2001 Preliminary Amendment to page 1, lines 10-12 of the present specification. Since the November 1998 priority date to which the present application is entitled is less than one year after the June 1998 issue date of the '704 patent, the '704 patent is not prior art under § 102(b).

Because the '704 patent is not prior art to the present application, it is respectfully submitted that all prior art rejections based on the '704 patent should be withdrawn.

18. The § 103(a) Rejection over Croughan 1994 and Terakawa

Claims 62, 64, 66, 68, 70, 75, 77, and 79 were rejected under 35 U.S.C. § 103(a) as being obvious over a proposed combination of Croughan 1994 and Terakawa.

For the record, it is Applicant's position that a person of ordinary skill in the art would have had no motivation to make the proposed combination of references. Applicant reserves the right to develop this argument at a later date should there appear to be a need to do so.

However, in the interest of simplifying the prosecution of this application, for the time being Applicant will instead show that, even assuming for the sake of argument that such a motivation had existed, there still would have been no reasonable expectation that the proposed combination of references would have successfully produced the claimed inventions.

As previously discussed, Terakawa does not disclose a rice plant that is resistant to a herbicide that "would normally inhibit the growth of a rice plant." Thus Terakawa gives no reasonable expectation that such rice plants might ever be produced, whether through the use of Terakawa's method or any other method.

The Croughan 1994 paper is inapposite. The February 11, 2003 Office Action at page 13 stated: "Croughan (1994) does not specifically teach that the isolated herbicide-resistant rice plant has a herbicide-resistant AHAS enzyme." In fact, the rice plant discussed in Croughan 1994 did not have a herbicide-resistant AHAS enzyme at all.

The herbicide-resistant rice discussed in Croughan 1994 is the same as that which was deposited with the American Type Culture Collection with accession number 75295. To confirm this identity, note the similarities between the brief description found in columns 2 and 3 of page 26 of the 1994 article and the more detailed description found at Col. 2, line 50 to Col. 4, line 9 of Croughan, U.S. Patent 5,545,822 (which is of record in the present application). Note also that the author of the article is the same as the inventor of the '822 patent -- namely, Dr. Timothy Croughan. Note also the chronology mentioned in col. 2, third full paragraph of page 26 of the article, and compare it to the priority filing date of the '822 patent. The article states that the herbicide-resistant line was identified in 1991, and that

further field evaluations were conducted in 1992. The priority filing date for the '822 patent was in August 1992, consistent with this chronology. Sample seed from the resistant rice line disclosed in the '822 patent was deposited with the American Type Culture Collection the same month, August 1992, and was given accession number 75295. See the '822 patent, Col. 4, lines 39-43.

However, the ATCC 75295 rice does not possess a herbicide-resistant AHAS enzyme at all. See Croughan, U.S. Patent 5,773,704 (which was cited by the February 11, 2003 Office Action), Col. 6, lines 4 through 64 (as corrected by the October 2, 2001 Certificate of Correction for the '704 patent). The mechanism of herbicide resistance expressed by ATCC 75295 is still unknown as of May 2003. However, that resistance is affirmatively known not to result from a resistant AHAS enzyme.

Thus the proposed § 103 combination of references, Terakawa and Croughan 1994, would be a combination of a first reference that does not disclose resistance to a herbicide that normally inhibits the growth of a rice plant, with a second reference that does not disclose a herbicide-resistant AHAS enzyme. Such a combination cannot provide any reasonable expectation of making the claimed inventions, which require a rice plant that expresses at least one functional acetohydroxyacid synthase that is resistant to a herbicide that normally inhibits the growth of a rice plant. Neither Terakawa, nor Croughan 1994, nor a hypothetical combination of the two gives any reasonable expectation of successfully producing a rice plant having a functional AHAS enzyme that is resistant to a herbicide that would normally inhibit the growth of a rice plant.

It is respectfully submitted that this ground of rejection should be withdrawn.

19-20. The Obviousness-Type Double Patenting Rejection

Claims 62, 64, 66, 68, 70, 75, 77, 79, and 81 were rejected for obviousness-type double patenting over Claims 1-9 of Croughan, U.S. Patent 5,773,704.

It is respectfully submitted that there are at least three different reasons why this ground of rejection should be withdrawn: **(a)** The February 11, 2003 Office Action applied an incorrect legal standard to the double patenting question. **(b)** Even if the standard applied in

the Office Action were legally correct (which it is not), that standard would nevertheless have been applied incorrectly to the facts of this case. **(c)** Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting.

(a) The standard applied in the February 11, 2003 Office Action concerning double patenting is legally incorrect. Without citing any supporting authority, the standard applied by the Office Action appears to be whether a person of ordinary skill in the art would be able to distinguish a derivative plant covered by the Claims of the '704 patent from a derivative plant covered by the claims of the present application.

This is not the correct legal standard for evaluating obviousness-type double patenting. The correct standard is instead the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph. Under the correct legal standard, the proper comparison is between two claims -- not a comparison between two embodiments.

Brief reflection will readily demonstrate that it would be inappropriate for the governing standard to be whether an embodiment covered by an issued patent could be distinguished from an embodiment covered by a claim in a pending application. As the discussion in M.P.E.P. § 804 demonstrates (e.g., subpart (II)(B)(1)(b)), obviousness-type double patenting questions often arise in the context of a broader genus claim versus a narrower species claim presented in different patent(s) or application(s). If the proper standard were merely whether embodiments could be distinguished, then obviousness-type double patenting would always exist between a genus claim and a species claim presented in different patent(s) or application(s), because an embodiment covered by a specific claim would always be covered by the generic claim. A large part of the discussion in the M.P.E.P. concerning double patenting would then be moot. However, comparison of embodiments is not the proper legal standard. Instead, one compares Claims.

(b) Even if the standard applied in the Office Action were legally correct (which it is not), the Office nevertheless would have incorrectly applied that standard to the facts of this case. Although it is not logically necessary for the Applicant to demonstrate this point in

order to overcome the double patenting rejection, it will nevertheless be discussed briefly, in case doing so might help accelerate the prosecution of this application. The Office Action stated at page 14: "Because the issued claims do not limit the number of generations away from the deposited plant, the herbicide-resistant rice plant of the instant claims would be obvious, because one of ordinary skill in the art would not be able to distinguish the 'derivative' plant of the patented herbicide-resistant rice plant from the 'derivative' plant of the instant claims."

As discussed above in connection with the § 112, second paragraph rejection, "derivative" plants must retain the specified herbicide resistance characteristics. The herbicide resistance characteristics are themselves typically distinguishable from one another. Different sources of herbicide resistance typically have different patterns of resistance to different levels of different herbicides. See, e.g., the present specification at page 24, lines 1-4, demonstrating that making such a determination is in fact relatively straightforward: "Further examination of these plants led to the conclusion that the following herbicide resistant lines appeared to be identical to prior herbicide resistant line ATCC 97523, presumably because a few seeds of ATCC 97523 from prior trials had remained dormant in the soil between growing seasons: PWC18, PWC20, PWC24, CMC25, CMC26, CMC28, CMC30, WDC32, WDC34, WDC35, and WDC36." (These lines were, accordingly, not among those deposited with ATCC.) Note in particular the last limitation of Claim 62: "wherein these derivatives of the plant with ATCC accession number 97523 that are excluded from the scope of this Claim are those that retain the herbicide resistance characteristics of the plant with ATCC accession number 97523."

In addition to examining patterns of resistance to various herbicides, it should also be kept in mind that, as previously discussed, it is a nearly universal practice in the art that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (except for a small number of proprietary hybrids). As a practical matter one is very likely to know the pedigree of any publicly released rice cultivar.

For either of these reasons, it will be possible for one of ordinary skill in the art to distinguish derivatives of ATCC 97523 covered by the '704 patent from rice plants covered by the present Claims, which exclude ATCC 97523 and its derivatives.

(c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting. The correct legal standard is the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

It is important to keep in mind that when "considering whether the invention defined in the claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art." M.P.E.P. § 804, subpart (II)(B)(1), sixth paragraph.

"Any obviousness-type double patenting rejection should make clear: (A) The differences between the inventions defined by the conflicting claims -- a claim in the patent compared to a claim in the application; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent." M.P.E.P. § 804, subpart (II)(B)(1), fifth paragraph.

The Office Action did not even attempt to apply this standard to the double-patenting question. To support this ground of rejection, at a minimum the Office should identify at least one specific Claim from the '704 patent and at least one specific Claim from the present application, and then explain why a person of ordinary skill in the art would conclude that the latter would have been obvious in light of the former. It is respectfully submitted, however, that this is not the case.

For example, Claim 1 of the '704 patent is as follows:

> **1.** A rice plant wherein:
>
> > **(a)** the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazaquin, primisulfuron, nicosulfuron,

sulfometuron, imazapyr, imazameth, imazamox, or a derivative of any of these herbicides;

(b) said plant is a derivative of the plants with ATCC accession numbers 75295 and 97523; and

(c) said plant has the herbicide resistance characteristics of the plants with ATCC accession numbers 75295 and 97523.

By contrast, Claim 62 of the present application reads as follows:

62. (once amended) A herbicide-resistant rice plant, wherein:

(a) the growth of said herbicide-resistant plant is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and

(b) said herbicide-resistant plant is a derivative of a rice plant obtained by exposing rice plants to mutation-inducing conditions; growing rice plants from the exposed plants, or growing rice plants from progeny of the exposed plants, in the presence of at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and selecting for further propagation rice plants that grow without significant injury in the presence of the herbicide; and

(c) said herbicide-resistant plant expresses a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant;

provided that excluded from the scope of this Claim is:

(d) a plant that is the plant with ATCC accession number 97523; and any mutant, recombinant, or genetically engineered derivative of the plant with ATCC accession number 97523 or of any progeny of the plant with ATCC accession number 97523; and any plant that is the progeny of any of these plants; wherein these derivatives of the plant with ATCC accession number 97523 that are excluded from the scope of this Claim are those that have the same herbicide resistance characteristics as the plant with ATCC accession number 97523.

Note first that Claim 62 expressly excludes derivatives of ATCC 97523. Thus Claim 62 of the present application and Claim 1 of the '704 patent are disjoint -- i.e., there is no overlap between the two Claims.

Note further that, as previously discussed, the ATCC 75295 line mentioned in Claim 1 of the '704 patent does not have a resistant AHAS enzyme.

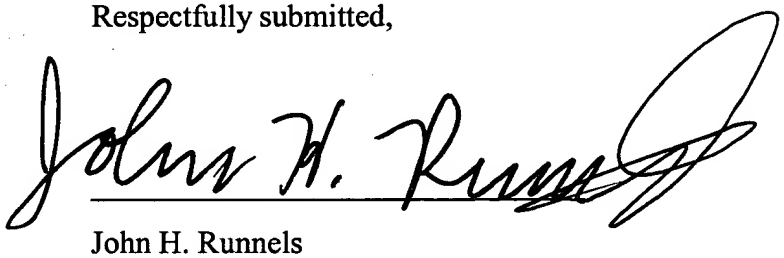
Nothing in Claim 1 of the '704 patent teaches or suggests any herbicide resistant rice plant having a resistant AHAS enzyme, other than the specific source of resistance from ATCC 97523. There is no suggestion for how to make such a plant, and there would have been no reasonable expectation that such a plant could be successfully produced. There would certainly have been no reasonable expectation that resistant rice AHAS enzymes could be produced having herbicide resistance characteristics different from those of the ATCC 97523 rice.

It is respectfully submitted that the obviousness-type double patenting rejection should be withdrawn.

Conclusion

Allowance of Claims 62-73 and 75-81 at an early date is respectfully requested.

Respectfully submitted,



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Appendix A: "Marked-Up" Versions of Amended Claims

64. (once amended) [A] The rice plant [as] recited in Claim 62, wherein the growth of said plant is resistant to inhibition by at least one imidazolinone herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant.

66. (once amended) [A] The rice plant [as] recited in Claim 62, wherein the growth of said plant is resistant to inhibition by at least one sulfonylurea herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant.

68. (once amended) [A] The rice plant [as] recited in Claim 62, wherein the growth of said plant is resistant to inhibition by at least one herbicide selected from the group consisting of imazethapyr, imazapic, imazapyr, nicosulfuron, sulfometuron methyl, imazaquin, primisulfuron, imazamox, chlorimuron ethyl, metsulfuron methyl, rimsulfuron, thifensulfuron methyl, tribenuron methyl, and pyrithiobac sodium; at levels of the herbicide that would normally inhibit the growth of a rice plant.

70. (once amended) [A] The rice plant [as] recited in Claim 62, wherein the mutation-inducing conditions comprise exposing rice seeds to a mutagen.

72. (once amended) [A] The process [as] recited in Claim 71, wherein the herbicide is selected from the group consisting of imazethapyr, imazapic, and imazapyr.

73. (once amended) [A] The process [as] recited in Claim 71, wherein said exposing step comprises exposing rice seeds to a mutagen.

77. (once amended) [A] The rice plant [as] recited in Claim 75, wherein the growth of said plant is resistant to inhibition by at least one imidazolinone herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant.

79. (once amended) [A] The rice plant [as] recited in Claim 75, wherein the growth of said plant is resistant to inhibition by at least one sulfonylurea herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant.

81. (once amended) [A] The rice plant [as] recited in Claim 75, wherein said plant is a derivative of the plant with ATCC accession number 75295, and said plant additionally has the herbicide resistance characteristics of the plant with ATCC accession number 75295.